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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,546	04/12/2004	Mark J. Whalen	25064/104/102	1795

5909 7590 02/28/2007  
NAWROCKI, ROONEY & SIVERTSON  
SUITE 401, BROADWAY PLACE EAST  
3433 BROADWAY STREET NORTHEAST  
MINNEAPOLIS, MN 554133009

EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/822,546	<b>Applicant(s)</b> WHALEN ET AL.	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 12/19/2006, amendment(s) to the specification, and new claim(s) 43-46 is/are acknowledged. The current rejections of the claim(s) 30-42 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 30, 34, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Engel et al (US 6,167,886 B1) as broadly as claimed. Engel et al discloses a lower urinary tract diagnostic system and methods of use thereof, comprising the steps of:

- positioning and supporting a prostatic urethra via catheter (43) having balloons (4, 5, and 27) (column 11 line 43 – column 12 line 18) by providing a diagnostic assembly comprising an elongate support member (as best seen in Figures 6-9) reversibly receivable within and for selectively supporting a prostatic urethra;

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- sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event (column 11 line 43 – column 12 line 18) via a pressure releasing valve (16);
- sequentially and incrementally retracting said elongate support member from the prostatic urethra via extracting said elongate support member from the urethra;
- manipulating a portion of said indwelling device so as to permit a prostate to physiologically act upon a prostatic responsive segment of said indwelling device (column 22 lines 8-63).and
- visually assessing urine flow associated with said sequential and incremental return of portions of the prostatic urethra to an unsupported condition (column 22 lines 8-63).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 31-33, 35-42, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engel et al in view of McRae (US 5,823,972) as broadly as claimed.

7. For claims 33, 37, and 38, Engel et al discloses a lower urinary tract diagnostic system and methods of use thereof, including the step of: obtaining a casting of the prostatic urethra via compressible ribs (column 11 lines 20-38).

8. Engel et al discloses the claimed invention except for explicitly disclosing ascertaining and assessing linear pressure relationships among the structures of the lower urinary tract and prostatic urethra patency during sequential and incremental manipulation of portions of the prostatic urethra to an unsupported condition whilst monitoring urine flow via visual assessment and pressure and volume monitoring and recording. McRae teaches ascertaining and assessing linear pressure relationships among the structures of the lower urinary tract and prostatic urethra patency during sequential and incremental manipulation of portions of the prostatic urethra to an unsupported condition whilst monitoring urine flow via visual assessment and pressure and volume monitoring and recording (column 4 lines 41-65, column 5 line 55 – column 6 line 33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lower urinary tract diagnostic system as taught by

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Engel et al, with the monitoring as taught by McRae for the purpose of increasing the efficacy of urinary tract treatment and monitoring.

***Response to Arguments***

9. Applicant's arguments with respect to claims 43-46 have been considered but are moot in view of the new ground(s) of rejection.

10. Applicant's arguments filed 12/19/2006 have been fully considered but they are not persuasive. Applicant argues (a) Engel et al does not disclose, teach, or fairly suggest sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event; (b) Engel et al does not disclose, teach, or fairly suggest manipulating a portion of the indwelling device to permit a prostate to physiologically act upon a prostatic responsive segment of the indwelling device; (c) neither Engel et al nor McRae disclose, teach, or fairly suggest a sequential and incremental urodynamic assessment; (d) there is no suggestion or motivation to combine Engel et al and McRae; and (e) neither Engel et al nor McRae disclose, teach, or fairly suggest the as claimed casting.

11. Regarding (a) the Examiner notes as broadly as claimed and as stated above, Engel et al discloses a lower urinary tract diagnostic system and methods of use thereof capable of sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event via a pressure releasing valve and associated indwelling structure associated therewith.

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12. Regarding (b) the Examiner notes as broadly as claimed and as stated above, Engel et al discloses a lower urinary tract diagnostic system and methods of use thereof including the insertion, manipulating, and extraction of a portion of the indwelling device to permit a prostate to physiologically act upon a prostatic responsive segment of the indwelling device (e.g. the pressure responsive balloon segments).

13. Regarding (c) and in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

14. Regarding (d) and in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Engel et al and McRae are concerned with lower urinary tract diagnostic system and methods of use thereof.

15. Regarding (e) and in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the disclosure of the casting in Figures 7-9 and pages 31-36 of the

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Specification) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

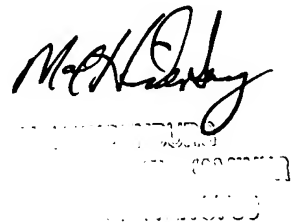


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH



Max F. Hindenburg  
Supervisor  
Art Unit 3736